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09/417,534	10/14/1999	ELKE BUCHA	209282.0006	7560

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	22

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/417,534	Applicant(s) BUCHA ET AL.	
	Examiner Gailene R. Gabel	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 12/18/02 is acknowledged and has been entered. Claims 1-6, 11, 13-16, 32, and 34 have been cancelled. Claims 39-51 have been added. Accordingly, claims 35-51 are pending and are under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

2. The rejections of claims 1-16, 32, and 34 under 35 U.S.C. 112 and 102 are now moot in light of Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 35-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35, part a) is vague and indefinite in reciting, "from monomers containing at least one structural element (A) derived from a carboxylic acid" because it fails to specifically define what the "monomers containing at least one structural element (A)" is intended to encompass. Specifically, claim 1, part a) does not recite the specific

composition or structure of the "monomers containing structural element (A)" except for the fact the structural element (A) is derived from carboxylic acid; thus, it is unclear how one would be reasonably apprised of the metes and bounds of the claimed invention. Claim 1, part a) is further indefinite for using a parenthetical symbol because it is unclear whether the limitation within the parenthesis are a part of the claimed invention. See also claim 39.

Claim 35, part b) is vague and indefinite in reciting, "at least one structural element (B) capable of establishing a hydrogen bond" because it fails to specifically define what the structural element (B) is intended to encompass. Specifically, claim 1, part b) does not recite the specific composition or structure of the "at least one structural element (B)" except for the fact the structural element (B) is capable of establishing a hydrogen bond; thus, it is unclear how one would be reasonably apprised of the metes and bounds of the claimed invention. Claim 1, part b) is further indefinite for using a parenthetical symbol because it is unclear whether the limitation within the parenthesis are a part of the claimed invention. Further, the term "capable of" fails to recite a positive limitation in the claim.

Claim 36 is indefinite in reciting improper, i.e. protein, cellular signal substance, a marker for a biological or synthetic substance, and overlapping, i.e. protein, nucleic acid, a partner of a biological or physiological affinity pair, Markush groups.

Claim 37 is indefinite in reciting overlapping, i.e. antigens, surface antigens, receptors, Markush groups.

Claim 45 has improper antecedent basis problem in reciting, "An interactive system according to claim 44".

Claim 47 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

Claim 48 is ambiguous because it is unclear what Applicant intends to encompass in reciting, "wherein the composition is comprised within a type of food".

Claim 49 is non-idiomatic and, therefore, confusing in reciting, "designer food".

Claim 51 is vague and indefinite in reciting, "adapted for treatment" because it is unclear how the interactive system is adapted, i.e. modified, to provide treatment.

Claim 51 is indefinite in reciting improper Markush groups, i.e. "selected from the group consisting of metabolic disorders, ... infections, etc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 35-36, 39-43, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniel (US 4,086,199).

Daniel discloses an interactive system which includes latex polymer particles which function as biological carriers for protein substances. The particles have a plastic

material (core) which comprises alkyl acrylates and methacrylates and a cross-linker comprising polyethylene glycol dimethacrylate which gives the polymer particles greater resistance to solvents (see columns 1-2). According to Daniel, the latex particles are very stable, chemically and mechanically, at extended periods of time, remain stable at varying pH levels and temperature (copolymerization temp ranges from 5 to 90 C). The biologically active substances such as proteins are coupled or adsorbed into the carrier particles (see column 4).

5. Claims 35-36, 39-42, 44, 47-51 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by DeCrosta et al. (US 4,575,539).

Decrosta et al. disclose a drug delivery system in the form of hydrogel beads including interpenetrating polymer network which have superior drug loading and release capacity (see Abstract). Specifically, DeCrosta et al. disclose a first polymer substrate comprising acrylic swelling agent, methyl methacrylate or acrylic acid, and a crosslinking agent, ethylene glycol dimethacrylate (see column 3, lines 21-36 and column 5, lines 10-17). The hydrogel beads are allowed to react at a temperature of from about 70C - 120C. The hydrogel beads are loaded with pharmaceutically active compositions wherein the loading is accomplished by coupling the pharmaceutically active compositions with the linker by swelling the hydrogel (see column 8, lines 34-64). The pharmacologically active drugs include those enumerated in column 6, lines 32-62. The drug delivery system allows oral delivery of pharmacologically active substances such as antibiotics for treatment of bacterial and parasitic infections as well as metabolic

diseases (see column 4, lines 24-42). Since all the elements recited in the claimed invention appear to be disclosed by DeCrosta, it is maintained that the features recited in the claimed invention, i.e. a stable interaction exists between the surface and the linker which comprises hydrogen bonds and which cannot be reversed by pH in the range of from 2-13 or temperatures up to 60 C, are inherently taught by DeCrosta.

6. Claims 35-51 are rejected under 35 U.S.C. 102(e) as being inherently anticipated by Hubbell et al. (US 5,410,016).

Hubbell et al. disclose an interactive system comprising photopolymerizable, biodegradable hydrogels used as tissue contacting materials or controlled release carriers (see columns 1 and 2, especially column 3, line 53 to column 4, line 27 and column 10, line 50 to column 11, line 17). Specifically, the interactive system has a polymerizable region which comprises dimethacrylates and oligomethacrylates. The polymerizable, macromer includes a core, an extension on each end, and an end cap wherein the core includes hydrophilic polyethylene glycol (see column 9, lines 7-18 and column 8, lines 5-48). The physiologically and pharmacologically active drugs coupled to the linker for controlled delivery include proteins, hormones, enzymes, antibiotics, and carbohydrates which include hyaluronic acid, heparin, and heparan sulfate (see column 10, lines 20-48). See especially Example 16. Since all the elements recited in the claimed invention appear to be disclosed by Hubbell et al., it is maintained that the features recited in the claimed invention, i.e. a stable interaction exists between the surface and the linker which comprises hydrogen bonds and which cannot be reversed

by pH in the range of from 2-13 or temperatures up to 60 C, are inherently taught by Hubbell et al.

Response to Arguments

7. Applicant's arguments filed 12/20/02 have been fully considered but they are not persuasive.

A) Applicant argues that Daniel does not teach or suggest the claimed invention because it does not teach the three components recited in claim 1, i.e. 1) a plastic material that is made from monomers and contains at least one structural element (A) derived from carboxylic acid, 2) a linker with at least one structural element (B) that is capable of establishing a hydrogen, and 3) a substance coupled to the linker. Applicant argues that Daniel instead only teaches polymer particle latexes wherein the particles comprise a core such as alkyl acrylates and methacrylates, that the monomer may be hydrogen bonded and also that it is provided with a cross-linker such as polyethylene glycol.

Contrary to Applicant's argument, Daniel, indeed, discloses latex polymer particles, i.e. an interactive system, which function as biological carriers for protein substances. The particles have a plastic material (core) which comprises alkyl acrylates and methacrylates, i.e. a plastic material that is made from monomers and contains at least one structural element (A) derived from carboxylic acid, and a cross-linker comprising polyethylene glycol, i.e. a linker with at least one structural element (B) that is capable of establishing a hydrogen, which gives the polymer particles greater

resistance to solvents. Daniel further discloses biologically active substances such as proteins coupled to the linker and adsorbed into the carrier particles. According to Daniel, the latex particles are very stable, chemically and mechanically, at extended periods of time, remain stable at varying pH levels and temperature, i.e. 5C to 90C. Therefore, it is maintained that claims 35-36, 39-43, and 47 are anticipated by Daniel.

B) Applicant argues that Daniel does not teach that the substance coupled to the linker is an anticoagulant.

In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., the substance coupled to the linker is an anticoagulant) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

C) Applicant argues that DeCrosta does not teach or suggest the claimed invention because it does not teach the three components recited in claim 1, i.e. 1) a plastic material that is made from monomers and contains at least one structural element (A) derived from carboxylic acid, 2) a linker with at least one structural element (B) that is capable of establishing a hydrogen, and 3) a substance coupled to the linker.

Contrary to Applicant's argument, Decrosta et al., indeed, disclose hydrogel beads, i.e. a drug delivery system, which include a first polymer substrate comprising

acrylic swelling agent, methyl methacrylate or acrylic acid, i.e. a plastic material that is made from monomers and contains at least one structural element (A) derived from carboxylic acid, and a crosslinking agent, (poly)ethylene glycol dimethacrylate, i.e. a linker with at least one structural element (B) that is capable of establishing a hydrogen. The hydrogel beads are loaded with pharmaceutically active substances by coupling the pharmaceutically active substance with the linker by swelling the hydrogel. The drug delivery system allows oral delivery of pharmacologically active substances such as antibiotics for treatment of bacterial and parasitic infections as well as metabolic diseases. Therefore, it is maintained that claims 35-36, 39-42, 44, 47-51 are anticipated by DeCrosta.

D) Applicant argues that DeCrosta does not teach that the substance coupled to the linker is an anticoagulant.

In response to applicant's argument that the reference fails to show certain features of applicant's invention, it is noted that the feature upon which applicant relies (i.e., the substance coupled to the linker is an anticoagulant) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Contrary to Applicant's argument, Hubbell et al., indeed, disclose photopolymerizable, biodegradable hydrogels , i.e. an interactive system, which comprises dimethacrylates and oligomethacrylates. The polymerizable, macromer

includes a core, an extension on each end, and an end cap wherein the core includes hydrophilic polyethylene glycol, i.e. linker. Hubbell et al. disclose coupling the physiologically and pharmacologically active drugs to the linker for controlled delivery of proteins, hormones, enzymes, antibiotics, and carbohydrates. Further, Hubbell et al. show in Example 16 wherein anticoagulants such as hyaluronic acid, i.e. heparin or heparan sulfate, are coupled to the polyethylene glycol linker.

8. For reasons aforementioned, no claims are allowed

Remarks

9. Prior art made of record are not relied upon but considered pertinent to the applicants' disclosure:

CHA et al. (US 5,665,428) disclose peptide/protein biodegradable drug delivery systems prepared as microspheres or hydrogels which are useful and stable at high temperatures, i.e. 50 C (see Abstract and column 6, lines 54-58). Cha et al. teach the microsphere as ABA block copolymers comprising a hydrophilic B block segment which is preferably polyethylene glycol, and a biodegradable hydrophobic A block segment which can be polyethylene carbonate. According to Cha et al., the release profile of the pharmaceutically active drugs from the polymers may be adjusted by the addition of carboxyl functional group into the hydrophobic block; thereby, further extending a sustained release of the drug (see column 9, lines 19-28). Column 9, lines 41-53 lists

pharmaceutically active polypeptides for use in the drug delivery system such as growth hormones, secretin, and gastrin, etc.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gail Gabel
Patent Examiner
Group 1641

3/22/03

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